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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/198,723	11/24/98	MALCOLM	B JB0800

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HM12/0615

EXAMINER

ZEMAN, R

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/198,723

Applicant
Malcom et al.

Examiner
Robert A. Zeman

Group Art Unit
1645



☒ Responsive to communication(s) filed on Nov 24, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) 12-28 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-28 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 and 7

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Priority

Applicants claim to priority based on U.S. Application No. 60/094,331 filed on July 28, 1998 and U.S. Application No. 60/067,315 filed on November 28, 1997 is acknowledged.

Election/Restriction

Applicant's election, without traverse, of Group I in Paper No. 8 is acknowledged. Claims 10 and 11 have been rejoined to Group I. Consequently, claims 12-28 are withdrawn from consideration by the examiner as they are drawn to a non-elected invention. Claims 1-11 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is rendered vague and indefinite by the use of the phrase "comprising the central hydrophobic domain". It is unclear what amino acids make up said domain. Nor is it clear what, if any, flanking regions Applicant is incorporating into said domain. As such it is impossible to determine the metes and bounds of the claimed invention.

Claims 2 is rendered vague and indefinite by the use of the term "at least about 4". As written it is unclear what constitutes the upper limit or the lower limit of said term. Is 7 "at least about 4"? What about 8 or 9? What about 3? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claims 3 and 4 are rendered vague and indefinite by the term "consisting essentially of". It is unclear what besides the claimed amino acids could be incorporated into the claimed linker. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Cell Vol 87, pages 343-355, October 18, 1996, IDS-7) in view of Dasmahapatra et al. (U.S. Patent 5,843,752).

Kim et al. disclose the 3 dimensional structure of the hepatitis C virus NS3 protease domain complexed with a synthetic NS4A cofactor peptide. Kim et al. further disclose that said complex has several important features including: the enzyme has a chymotrypsin-like fold and the activation region of NS4A forms a β strand that intercalates into the N-terminal domain β sheet in the core of the enzyme. The structure disclosed by Kim et al. suggests fusing the C-terminus of the essential portion of the NS4A peptide to the N-terminus of the catalytic domain using an appropriate spacer to abrogate the need for an exogenous cofactor (see page 351). Kim et al. differ from the claimed invention in that they don't disclose the recombinant expression of a protein wherein the C-terminus of the essential portion of the NS4A peptide is fused to the N-terminus of the catalytic domain using an appropriate spacer. Dasmahapatra et al. disclose soluble covalent HCV NS3-NS4A complexes comprising the catalytic domain of native HCV NS3 protease fused to an HCV cofactor, wherein the cofactor has been modified to prevent cleavage by the HCV NS3 protease (see Example 1, column 9-11). Dasmahapatra et al, disclose

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not only methods for constructing recombinant fusion proteins, they disclose the sequences for both NS4A and NS3. It would have been obvious to one of skill in the art to use the recombinant methods and sequences disclosed by Dasmahapatra et al. to produce the fusion protein suggested by the 3 dimensional modeling disclosed by Kim et al. in order to obtain a fusion protein with a 3-dimensional structure that accurately models the natural conformation of the HCV protease and cofactor.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Anthony Caputa, can be reached at (703)308-3995.

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Robert A. Zeman

June 14, 2000

A handwritten signature in black ink, appearing to read 'D. Wortman', with a long horizontal flourish extending to the right.

DONNA WORTMAN
PRIMARY EXAMINER